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Dated: 12/23/04 Signature: Barbara J. Miller
(Barbara J. Miller)

Docket No.: 05627-00005-USA
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

considered on 3/18/05
In re Design Application of:
A. J. Mixson

Application No.: 10/018103

Art Unit: 1632

Filed: November 5, 2001

Examiner: D. T. Nguyen

For: HISTIDINE COPOLYMERS AND METHODS
FOR USING SAME

Declaration Under 37 C.F.R. § 1.132

Dr. A. James Mixson declares as follows:

1. I am the sole inventor named on the above-referenced patent application.
2. I have read the Office Action dated August 25, 2004.
3. Claims 1-10 and 12-52 have been rejected as lacking enablement in view of a teaching in Midoux (U.S. Pat. No. 6,372,499) that polyhistidine is very poorly soluble in an aqueous medium at neutral pH, and that it is not capable of forming stable complexes with DNA at neutral pH.
4. Exhibit A is a copy of lab notes describing an early experiment that I conducted with a histidine copolymer having a low lysine:histidine ratio of 1:8. A ratio of 1:8 to selected specifically because this low K:H ratio peptide with a high percentage of histidines (89%) would be more likely to precipitate in view of the known poor solubility of polyhistidine. However, I found that this polymer did not precipitate at a pH of approximately 7.0 at two different concentrations. Exhibit A (see notes following the numbers "2" and "3", wherein "ppt." represents the common abbreviation of "precipitation"). In addition, we found that a histidine copolymer:DNA complex formed using this peptide did not precipitate either. Exhibit A (see note following number "5"). Based on these results, this experiment established that a peptide having as high as 89% histidine residues remained soluble.